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Monday, June 26, 2000

Business

Organogenesis Pres & CEO - Interview  
 Bill Griffeth

Power Lunch

BILL GRIFFETH, CNBC ANCHOR, POWER LUNCH: Organogenesis is the company that recently received FDA approval for its lead product known as Aligraf, to be used to treat diabetic foot ulcers. Now, it's a skin substitute. You may know this product. It's been sold here in the U.S. since 1998 to treat leg ulcers caused by poor circulation. Now it has FDA approval for this second application and we'll talk about some of future applications it may be used for.

Joining us today to talk about his company, Philip Laughlin is the President and CEO of Organogenesis. Nice to see you again. Welcome back. PHILLIP LAUGHLIN, CEO, ORGANOCENESIS: Hi, Bill. Thanks for having me on your show.

GRIFFETH: Congratulations on this latest application. When will we see it in the marketplace for that?

LAUGHLIN: It is in the marketplace now. We got approval last week for treating diabetic foot ulcers, which is incredibly exciting for us.

GRIFFETH: When will it be used for that purpose?

LAUGHLIN: Today.

GRIFFETH: They can use it today? Yeah?

LAUGHLIN: Today.

GRIFFETH: Pretty cool. Do you know of anybody who is doing it right now?

LAUGHLIN: Absolutely. It was on the market before for other indications.

Some doctors were using it for diabetic foot ulcers, but at a very low

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GRIFFETH: It's exactly the same product or is there a slight variation for the new application?

LAUGHLIN: It is exactly same product, but a new indication.

GRIFFETH: And I have some e-mail questions from viewers on this specific topic. And Clay wants to know whether the foot ulcer treatment will be covered by Medicare and Medicaid. Do you know?

LAUGHLIN: Right now we are in discussions with Medicare on reimbursement. We do not yet have standardized reimbursement from Medicare and that's an issue for us because many of our patients are Medicare patients.

GRIFFETH: Right. I mean I've heard from other viewers on, not just on this, but on the other application, the first application as well, does that put essentially a cap on your ability to sell this product if it is not covered by certain insurance products?

LAUGHLIN: It slows us down. I think that the good thing for the patients is that diabetic foot ulcer is such as a serious ailment, it is life threatening and results in many amputations each year, that that puts more pressure on Medicare to provide coverage for the product.

GRIFFETH: What is their reticent so far?

LAUGHLIN: The issue is that, you know, we are -- we are a tissue engineering company and these are living cells. The product is actually a living cell product. So we don't fall into any nice neat box for them and that's been a struggle, how to treat us.

GRIFFETH: I mean, we should say it's a combination of some human skin cells and cow collagen, right?

LAUGHLIN: It is cow collagen which is non-cellular to provide structure but the main ingredients are two different types of human cells, your epidermal and dermal layer of cells, which is your upper layer and your bulk layer.

GRIFFETH: Right. A question from Melanie in Phoenix. She wants to know what the incidence of rejection is for this type of treatment?

LAUGHLIN: We have never had a rejection with Apligraf. That's one of the major technology breakthroughs of the product.

GRIFFETH: And the next question which I happen to know the answer but will let this person ask, it leads into your third application. Does this technology have applications for facial cosmetic surgery?

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LAUGHLIN: Yes, it does in cosmetic in the sense of avoiding disfigurement, not cosmetic in the sense of making us beautiful. If you have a skin cancer removed from the center of your face, this would reduce scarring. We are in clinical trials right now to prove that to the FDA that it works to reduce scaring.

GRIFFETH: I would imagine you have this patented but can it be reformulated in some ways that competition might get out there and take you on with this?

LAUGHLIN: There's always a risk of competition. Yes, we have lots of patents. Could other companies try to get on the market and use the different approaches? Yes, they could. There are quite a few companies that have tried so far. No other company has brought a living, a mass manufactured living cell product to the market.

GRIFFETH: And the profitability question inevitably has to come up at some point. Do you have a timetable yet now that you're starting to get FDA approval for new and more, you know, widely used applications here?

LAUGHLIN: Well, the good news is that even know we have a full pipeline of other products, we can become profitable and will become profitable with Aligraf alone. The two main drivers of that are diabetic foot ulcer removal which happened last week and getting that standardized Medicare reimbursement, which has been slow going. We're optimistic. It hasn't opened yet.

GRIFFETH: Yeah, and future applications, I mean beyond the treatments or skin cancer, what else do you think you could be working on here?

LAUGHLIN: The other could be decubitis (ph) ulcers which is bed sores. Also burns. We don't have indications for those. There are certainly plenty of other applications for the technology but those are different products.

GRIFFETH: Do you choose the potential markets based on the size of the market or the need, you know, or the urgency of the need? How do you choose future markets for your applications?

LAUGHLIN: Both. And in the case of diabetic foot ulcer, it is both. It's the largest market and I see it as the most serious because it is life threatening. The infection from these ulcers results in amputations. The survival rate if you were to have an amputation at three years is only 20 percent.

GRIFFETH: Interesting. Mr. Laughlin, good to see you. Good luck with that. Thanks.

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LAUGHLIN: Thanks for having us on the show.

GRIFFETH: All right. Philip Laughlin, President and CEO of Organogenesis, joining us from Boston today. Here's what the company's stock has done the past year. It's been a roller coaster ride. It's been caught up in a lot of the biotechnology euphoria of this year. Today it's unchanged at 11 3/4.

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